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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,047	02/19/2004	Michael Pesachovich	1662/62102	5742

26646 7590 03/13/2006

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NEW YORK, NY 10004

EXAMINER
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GEHMAN, BRYON P

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/782,047

Applicant(s)

PESACHOVICH ET AL.

Examiner

Bryon P. Gehman

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3728

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12 and 16 are finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12, line 2, "the package" lacks antecedent basis and should be --the container--. As to claim 16, the phrase "HPLC relative to retention times of about 0.26, 0.34, 0.37, or 0.80" is indefinite, as it is not clear what the retention times are relative to to form a termless ratio, nor is it clear that the "retention times" are ratios as opposed to raw times. It would appear the comparison to azithromycin and a reference to "relative retention times" would be necessary to correlate this statement to page 7 of the specification, as argued by applicants.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 3728

4. Claims 1-14 and 16 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Tenengauzer et al. (6,764,997). Disclosed is a container for packaging azithromycin made of gas impermeable material wherein after storage azithromycin degradation products are limited (see column 2, lines 51-62 and Table 6).

As to claims 3-4 and 9-10, a laminated aluminum bag is disclosed (column 16, lines 42-47).

As to claim 5, the azithromycin is disclosed in a solvate form.

As to claims 7 and 8, azithromycin monohydrate is disclosed

As to claim 13, the disclosed test occurred at 55 degrees C.

As to claim 14, 60% relative humidity is ordinary atmosphere as disclosed.

5. Claims 17-19 are finally rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tenengauzer et al.. See the immediately preceding paragraph. The methodology is simply the use of the described structure.

6. Claims 1-4 and 10-15 are finally rejected under 35 U.S.C. 102(e) as being anticipated by Schuler et al. (2005/0051453). Disclosed is a sealed container for packaging azithromycin made of gas impermeable material wherein after storage azithromycin degradation products are inherently limited (see page 3, section 37 and page 7, section 54) by use of a laminated aluminum bag.

As to claim 11, the gas impermeable material is impermeable to oxygen.

As to claim 12, it is disclosed that the gas impermeable aluminum is on the interior of the container.

As to claims 13-16, the functional parameters would be inherently provided by the disclosed container.

7. Claims 17-19 are finally rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schuler et al.. See the immediately preceding paragraph. The methodology is simply the use of the described structure.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5-9 and 14-16 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Tenengauzer et al. and Schuler et al.. To any degree the forms of azithromycin and previously held inherent parameters can be argued as not expressly disclosed, these features are held to be obviously attainable given the disclosure of either one of Tenengauzer et al. and Schuler et al. with respect to azithromycin in general.

10. Claims 1-16 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Lechzik et al. (3,331,495) in view of any one of Curatolo et al. (5,605,889), Tenengauzer et al. and Schuler et al.. Claims 1-16 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler et al. (2004/0104142) in view of any one of Curatolo et al. (5,605,889), Tenengauzer et al. and Schuler et al.. Lechzik et al. and Dobler et al. each disclose a container for packaging degradable medicine made of gas impermeable material wherein after storage degradation products of the medicine are inherently limited by use of a sealed laminated aluminum bag. Curatolo et al., Tenengauzer et al. and Schuler et al. each disclose providing azithromycin in a protective container. To modify the container of either one of Lechzik et al. and Dobler et al. to employ the container specifically for azithromycin would have been obvious in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al. in order to protect the azithromycin from degradation, as disclosed by either one of Lechzik et al. and Dobler et al..

As to claims 3-4 and 9, a laminated aluminum structure is disclosed by either one of Lechzik et al. and Dobler et al..

As to claims 5-8, the azithromycin is disclosed or suggested in various forms by one of Curatolo et al., Tenengauzer et al. and Schuler et al..

As to claims 13-16, to the degree the previously held inherent parameters can be argued as not expressly disclosed, these features are held to be obviously attainable given the disclosures of the prior art taken as a whole.

11. Claims 17-19 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Lechzik et al. in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al.. Claims 17-19 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler et al. in view of any one of Curatolo et al., Tenengauzer et al. and Schuler et al.. See the immediately preceding paragraph. The methodology is simply the use of the described structure.

12. Applicant's arguments filed February 10, 2006 have been fully considered but they are not persuasive. Applicants' arguments with respect to the veracity of claim 16 with respect to page 7 of the disclosure is not found convincing, as the language at page 7 is not the same as employed in the claim, and it is not clear that ratios are being defined in the claim.

With respect to claim 1 and Tenengauzer et al., applicants argue that Tenengauzer et al. do not disclose a container for packaging azithromycin comprising a gas impermeable material which can limit degradation products to no greater than 5%. However, Tenengauzer et al. disclose a container for packaging azithromycin, wherein the package with the disclosed azithromycin contained therein, has the azithromycin degrade to less than the claimed degradation as clearly explained at page 2, lines 51-62 and column 16, Table 6. Applicants' claimed container does not contain azithromycin and the employment of azithromycin including an antioxidant is not precluded by the claim. The employment of the azithromycin and laminated aluminum bag container of Tenengauzer et al. in combination will result in degradation products less than 5%, even

Art Unit: 3728

3% by weight of the azithromycin, therefore, the container comprising gas impermeable laminated aluminum will function to have degradation products not exceed 3% if provided with the azithromycin of Tenengauzer et al.. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

All of applicants' arguments with respect to the remaining references are basically that the prior art, which discloses the structural features of applicants' claimed invention, do not describe the functional features of applicants' claims. It would appear that degradation prevention of the content is sought and obtained to a major degree by each of Tenengauzer et al., Schuler et al., Lechzik et al., Curatolo et al. and Dobler et al., the matter of degree being the only question. The fact that applicants have recognized another advantage (or described a desired advantage in a particular way) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The evidence, when comparing applicants' disclosures to those of the prior art, would indicate that the claimed container would have been, if not anticipated by the prior art, to have been obvious to derive to one of ordinary skill in the art. There is no evidence that one of ordinary skill in the art,



Art Unit: 3728

given the teachings of Tenengauzer et al., Schuler et al., Lechzik et al. Curatolo et al. and Dobler et al., would not derive a functional limit of degradation similar to that as claimed by applicants following the teachings of the prior art employed against the applicants' claims.

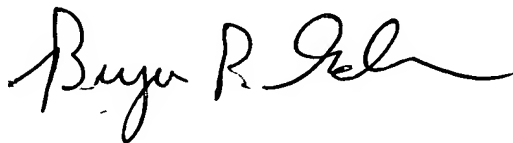
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Monday through Wednesday from 5:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Bryon P. Gehman". The signature is fluid and cursive, with the first name "Bryon" being the most prominent part.

Bryon P. Gehman  
Primary Examiner  
Art Unit 3728

BPG